

REMARKS

By this amendment, claims 79, 80, 82, 86, 88, and 91 have been amended and claims 81 and 94 have been cancelled without prejudice. Claims 47-78 remain withdrawn from consideration and, thus, claims 79-80, 82, 86-93, and 95 are currently under examination in the present application. For the reasons set forth below, Applicants submit that the present amendments and arguments place this application in condition for immediate allowance.

As an initial matter, by the present amendments, claim 79 has been amended to indicate that the apparatus of the present invention is adapted to measure electrical current “flowing through sub-dermal tissue or subcutaneous body tissue,” as was previously recited in claim 82, but which has now been cancelled without prejudice by virtue of the present amendments. Additionally, by the present amendments, claim 79 has also been amended to clearly indicate that the apparatus comprises a pair of injection electrodes and a pair of sensing electrodes such that the apparatus is directed toward a “4-point” embodiment described in paragraphs [0029] and [0031], Example 3, and throughout the specification of the present application. In light of these amendments to claim 79, corresponding amendments have also been made to claims 80, 82, 86, 88, and 91. Each of these further amendments are fully supported by the specification of the present application, as filed, and, accordingly, no new subject matter has been added by the amendments to claims 79, 80, 82, 86, 88, and 91.

In the Office Action dated December 10, 2009, the Examiner rejected claims 79-82, 88-89, and 91-93 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent

Application Publication No. 2003/0216663 ("Jersey-Willuhn") in view of U.S. Patent Application Publication No. 2003/0130616 ("Steil"). The Examiner also made various rejections to claims 86, 87, 90, 94, and 95 under 35 U.S.C. §103(a) as being unpatentable over Jersey-Willuhn and Steil in combination with U.S. Patent Application Publication No. 2004/0182719 ("Purvis"), U.S. Patent Application Publication No. 2002/0049389 ("Abreu"), U.S. Patent No. 7,315,767 ("Caduff"), or U.S. Patent Application Publication No. 2003/0220581 ("Ollmar"). In particular, in rejecting the claims, the Examiner asserted that, although Jersey-Willuhn fails to disclose a processor for correlating a measured impedance and determining glucose levels, it would have been obvious to include such a processor in the physiological monitor described in Jersey-Willuhn because Steil indicates that tissue impedance can be used to measure blood glucose concentration. For the reasons set forth below, Applicants submit that these rejections are respectfully traversed and should be withdrawn.

As reflected in the claims of the present application, as amended, the present invention relates to an apparatus for measuring or monitoring blood glucose levels in a subject that is adapted to measure impedance of an electrical current flowing through sub-dermal or subcutaneous body tissue and to correlate those impedance measurements to a blood glucose level. Typically, the stratum corneum of subject's skin exhibits a high impedance to electrical current and, as such, measurements at the skin surface are often subject to impedance effects that give rise to erroneous readings. Applicants have found, however, that by using an apparatus that includes at least one pair of current-injection electrodes and at least one pair of sensing electrodes, an electrical current can be injected

into sub-dermal or subcutaneous body tissue underlying the stratum corneum of the skin and then received by the sensing electrodes such that the impedance of the current can be measured and then correlated with glucose levels to thereby accurately calculate blood glucose levels in a subject. Indeed, as described in Example 3 of the present application, two injection electrodes and two sensing electrodes can be positioned at different locations on the legs of a subject and current can then be passed through the two injection electrodes such that the resulting voltage is received independently by the two sensing electrodes. In this regard, the present invention thus offers an advantage over existing systems as the injection of current into the deeper strata of the skin, which includes a higher moisture content and has lower impedance characteristics, subsequently allows for an accurate calculation of blood glucose levels.

In contrast to the present application, Jersey-Willuhn is directed to a system for monitoring edema or blood clot development during an intravascular infusion that is designed to detect edema, or a cascade of tissue alterations leading to edemas, and is also designed to yield a 3-D image of such alterations. However, there is no teaching or suggestion in Jersey-Willuhn that its system can or should be utilized for correlating electrical impedance to blood glucose levels, much less any teaching or suggestion that such a correlation can be done using an apparatus such as the one described and claimed in the present application.

In the Office Action, the Examiner asserted that paragraph [0154] of Jersey-Willuhn indicates that its system can be used to measure glucose concentration. However, that portion of the reference merely indicates that measurement of glucose can

be accomplished by sensors that are “incorporated into the flexible dressing” and further indicates that the glucose measurement is accomplished by sensors that incorporate an enzyme that reacts with glucose to generate an electrical signal. As such, it is thus the case the Jersey-Willuhn does not teach or even remotely suggest an apparatus such as that claimed in the present application whereby at least one pair of current-injection electrodes and at least one pair of sensing electrodes are included and directly used to measure an impedance of an electrical current flowing through sub-dermal or subcutaneous body tissue in a subject such that impedance measurements can be correlated to a blood glucose level.

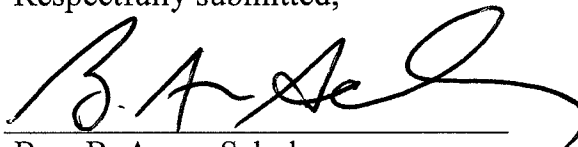
Similarly, Steil also does not teach or remotely that such an apparatus can effectively be used to measure electrical impedance and calculate a blood glucose level. As indicated in the previous response in this case, Steil describes a closed loop infusion system that controls the rate that a fluid is infused into the body of a user and can monitor the glucose concentration in the body of the user when insulin is being infused by the system. The infusion system described in Steil includes a controller, a delivery system, and a sensor system, which includes a working electrode, a reference electrode, and a counter electrode (see, e.g., para. [0319]). However, there is no teaching or suggestion whatsoever in Steil that at least one pair of current-injection electrodes and at least one pair of sensing electrodes could be used for measuring impedance and calculating blood glucose levels, as is the case in the present application. Instead, Steil clearly teaches that all three electrodes are required to form a circuit which can then be used to measure the observed impedance, and there is no indication in Steil that its three-electrode format

could be altered such that a pair of current-injection electrodes and a pair of sensing electrodes could be used for measuring impedance and calculating blood glucose levels. Moreover, the cited Purvis, Abreu, Caduff, and Ollmar references add nothing further in this regard, and were merely cited by the Examiner for their teachings with respect to amperometers and voltmeters, processors, arrangement of electrodes, and impedance depths.

Accordingly, Applicants respectfully submit that the claims of the present application are not anticipated or rendered obvious by the cited Jersey-Willuhn, Steil, Purvis, Abreu, Caduff, and Ollmar references and, accordingly, Applicants thus submit that the Examiner's rejection is respectfully traversed and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections, and has been placed in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,



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